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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,651	09/09/2003	Mark A. Reiley	29914-701.410	1980

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EXAMINER

ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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07/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/658,651

Applicant(s)

REILEY, MARK A.

Examiner

DAVID J. ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 39-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Election/Restrictions

Claims 39-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/29/2007.

Applicant's election with traverse of group 1 and species as illustrated in figure 24 in the reply filed on 3/29/2007 is acknowledged. The traversal is on the ground(s) that the method requires the prosthesis of the product claims. Or the product must be used by method as set forth in the method claims. This is not found persuasive because the product may be used to support any joint function including the vertebral joint as claimed. In fact the prosthesis does not require any removal of vertebral body.

With respect to the species, according to MPEP 809.02, restriction between the various embodiments as illustrated in the figures and as supported by applicant's disclosure is proper. While the claim(s) may be generic, for the purpose of examination, the elected figure allows for clearer understanding of the distinct features of the elected species that is being claimed. In this instance, applicant as stated that claims 1-38 all are readable on the elected figure 24. However, due to the attempt to define the claimed invention with the language of "adapted and configured to replace" it is not clear if all the claims as argued by applicant's representative are readable on the elected figure 24. For the purpose of clarity, the restriction between species will ensure a clear

and complete record regarding the metes and bounds between the various illustrated embodiments as disclosed in the specification.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to a prosthesis system comprising:

A caudal prosthesis that may be fixed at or near a pedicle. The caudal prosthesis includes a joint structure. The system further includes a cephalad prosthesis that may be fixed to the superior vertebral body at or near a pedicle. The cephalad prosthesis includes a joint structure that is to articulate with the caudal prosthesis.

Claim 2, it is not clear how the structure of the device is further defined (as illustrated in elected figure 24) by the function of "adapted and configured to replace a natural articular process". It appears that the structure as set forth in claim 1 and as illustrated in figure 24 is not further modified by the method steps of claim 2. In fact, it appears that the device as shown in figure 24 is utilized in each method as claimed in claims 1 and claim 2, respectively. (i.e. how does the structure of claim 2 differ from the structure of claim 1?).

Art Unit: 3738

The same questions of indefiniteness are also applicable with respect to claims 3-26.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of Wall [4633722], Homsy, et al [4778472], Morgan [4917701] and Zang [5314486]

The term "adapted and configured" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This language, absent structural features, relies solely on a functional use (ie. to replace a certain anatomical feature). It is not clear from the specification, what form of modification or structure would be inherent in the device after removal of at least some portion of the various anatomical structures as set forth in claims 2-26

Each reference illustrates a prosthesis that includes a prosthesis body for fixation to an anatomical bone structure and an artificial joint structure carried by the prosthesis body. In each instance, the devices are capable of performing the function as broadly set forth in the claims.

Art Unit: 3738

With respect to claims 27 and 28, each device is made from a medical material from the group of known materials.

Claim 29, the system in each of Wall, Homsy, Morgan and Wall includes a fastening element that is adapted to be installed within a bone.

Claim 30 see screw fasteners in any of Wall, Homsy or Morgan.

Claim 31, see stem of Zang.

Claims 32 and 38, the stem utilizes cement and the screw threads inherently resisting rotation after installation.

Claims 33 and 37, see cement of Zang.

Claim 34, see ingrowth material as taught by Homsy or Wall.

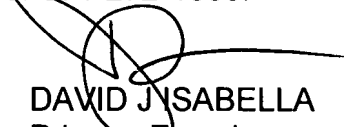
Claims 35 and 36, see screws in any of Homsy, Morgan and Wall.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
7/7/2007